Docket Number: EPA-HQ-OPP-2009-0327
www.regulations.gov

Tebuthiuron Final Work Plan (FWP) for Registration Review March 2010

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Case Number: 0054

Approved by:

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Director
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Date: 3.12.2010

Introduction:

This is the Environmental Protection Agency's (EPA or the Agency) ***Final Work Plan*** (FWP) for the registration review of tebuthiuron. The FWP includes the expected registration review time line. The FWP also addresses public comments received concerning the ***Preliminary Work Plan*** (PWP) in the ***Summary Document*** which was posted in the tebuthiuron registration review docket (EPA-HQ-OPP-2009-0327) and any other comments concerning the initial docket postings. The ***Summary Document*** provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the registration review program and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

Tebuthiuron was the subject of a 1994 Reregistration Eligibility Decision (RED), and the Tolerance Reassessment Eligibility Decision (TRED) was completed in 2002. Tebuthiuron is a systemic, relatively nonselective urea herbicide which is absorbed into the plant roots and is then translocated into the plant. Once absorbed and translocated into the plant, it acts by inhibiting photosynthesis. It is registered for use to control broadleaf and woody weeds, grasses and brush on feed crop sites. Primary use sites include rangeland, near railroads, and other industrial facilities. There are no residential or public recreational uses for tebuthiuron. Compound 104, the toxicological degradate of concern, is assumed to have equivalent toxicity to tebuthiuron parent because of its structural similarity to its parent compound.

Updates since the Summary Document:

The Tebuthiuron Summary Document identified anticipated data needs in order to conduct a complete ecological risk assessment for tebuthiuron, including an endangered species assessment. Based upon the comments received during the public comment period and further review of the Agency's database, the Agency determined that the following data are no longer required under registration review for tebuthiuron:

- OPPTS GLN 850.1055 Embryo Larval Toxicity
- OPPTS GLN 850.1035; 850.0045 Crustacean Acute Toxicity
- OPPTS GLN 850.1300 Aquatic Invertebrate Life Cycle
- OPPTS GLN 850.1400 Freshwater Fish Early-Life Stage Toxicity

The Summary Document also noted additional human health data needs that the Agency anticipated requiring. A confined field rotational crop study (GLN 860.1900) was listed as required, unless Dow AgroSciences provided information that demonstrates to the Agency that the pastureland use area is either insignificant in acreage or is predominantly perennial grasses that are not rotated annually. During the 60-day comment period, Dow AgroSciences provided the Agency with adequate information pertaining to pasturelands and perennial grasses. The information indicated that most land treated with tebuthiuron is not retreated for 10 to 15 years, if ever. Tebuthiuron is only used for the restoration of natural grassland vegetation in rangeland, permanent pastures and in non-cropland areas such as energy and transportation rights-of-way. Annual grasses have a low tolerance to tebuthiuron and can be significantly damaged by broadcast applications as low as 0.3 lb ai/acre. Since tebuthiuron is a residual herbicide that expresses its activity over several years, use on annual crops is precluded. The Agency determined that this information is adequate; therefore, a rotational crop study is no longer required under registration review for tebuthiuron.

Additionally, in accordance with the revised 40 CFR Part 158 data requirements, the Agency anticipated requiring a neurotoxicity battery (acute and subchronic studies) (GLN 870.6200). Upon evaluation of the available studies along with the information provided by Dow AgroSciences, (use pattern in years and used on non-cropland areas), the Agency determined that the neurotoxicity battery (acute and subchronic studies) are no longer required for tebuthiuron under registration review.

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Tebuthiuron is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all

pesticide chemicals. Accordingly, EPA anticipates issuing EDSP orders/data call-ins for all Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Comments Received on the Preliminary Work Plan:

The Agency received comments during the 60-day public comment period on the initial tebuthiuron docket, which opened on September 23, 2009, and closed on November 23, 2009. A description of the comments and EPA's responses to the comments are provided in the "Summary of Comments and Agency Responses" section of this document. The comments did not affect the risk assessments to be performed, or the projected registration review timeline as described in the PWP. However, as noted previously, the comments/information that Dow AgroSciences provided changed some of the Agency's anticipated data needs (see *Updates since the Summary Document* section for details on the changed anticipated data needs). Therefore, this document finalizes the work plan for the tebuthiuron registration review process.

In the PWP, EPA also solicited comments on three specific topics: environmental justice, water body impairment, and trade irritants. No comments or information were received during the public comment period concerning these issues.

Risk Assessment and Data Needs:

The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species assessment, for all pesticide uses of tebuthiuron. The Agency anticipates conducting a human health risk assessment.

Ecological Risk:

- The most recent ecological assessment was completed in 1994 in support of the Tebuthiuron Reregistration Eligibility Decision (RED).

- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether tebuthiuron's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.

- For the ecological assessment, the Agency will consider the parent tebuthiuron as well as the degradate of concern, compound 104.

- The Agency anticipates requiring the following data for parent tebuthiuron in order to conduct a complete ecological risk assessment for tebuthiuron, including an endangered species assessment:

    - OPPTS GLN 835.6200 Aquatic field dissipation
    - OPPTS GLN 850.1075 Marine/estuarine fish acute toxicity
    - OPPTS GLN 850.1025 Bivalve acute toxicity on shell deposition
    - OPPTS GLN 850.4100 Tier II Seedling emergence toxicity
    - OPPTS GLN 850.4150 Tier II Vegetative vigor
    - OPPTS GLN 850.2100 Avian acute oral toxicity study testing a passerine species
    - OPPTS GLN 850.2200 Avian reproductive toxicity study (testing exposure concentrations ranging from > 100 ppm to at least up to 810 ppm)

- Refer to the document, *Registration Review Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Tebuthiuron*, located in the docket, for a detailed discussion of the anticipated ecological risk assessment and data needs as of the PWP.

Human Health Risk:

- The most recent dietary risk assessment was conducted in April 2002 in support of the Tebuthiuron Tolerance Reassessment Eligibility Decision (TRED).

- The Agency anticipates conducting a new dietary assessment for tebuthiuron.

- Since the Agency plans to update the drinking water exposure assessment for tebuthiuron to directly incorporate drinking water residues into the dietary risk assessment (food and water), a cumulative residue approach will be applied to model total tebuthiuron residues (tebuthiuron parent plus compound 104) for the drinking water assessment in registration review.

- The Agency anticipates conducting a reevaluation of the total dietary burden for beef and dairy cattle using feedstuffs to support the reassessment of established tebuthiuron tolerances on animal commodities.

- There are currently no residential or public recreational uses for tebuthiuron; therefore, the Agency will not be conducting a residential assessment.

- Occupational exposures have not been considered quantitatively in any existing risk assessment to date for tebuthiuron; however, given the use

patterns, occupational exposures can occur. Therefore, the Agency anticipates conducting an occupational handler risk assessment in registration review based on the current tebuthiuron use patterns.

- Postapplication worker exposures are not expected to occur because tebuthiuron is applied to sites where reentry is unlikely. An assessment for these type of tasks has not been completed and would not be warranted unless use patterns change in the future.

- The Agency anticipates requiring the following data for parent tebuthiuron in order to conduct a complete human health risk assessment for tebuthiuron:

  - An immunotoxicity study (GLN 870.7800). This is a new data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses).

- Since the 2002 TRED, EPA received the requested mammalian erythrocyte micronucleus test study (GLN 870.5385). Upon review of that study, EPA will evaluate the mutagenic potential of tebuthiuron.

- Upon receipt, and review of the anticipated data, the Agency will reevaluate the points of departure and uncertainty factors for the dietary assessments.

- Please refer to the document, *Tebuthiuron – Registration Review Scoping Document for Human Health Assessments*, located in the docket, for a detailed discussion of the anticipated risk assessment needs and data needs as of the PWP.

Timeline:

EPA has created the following estimated timeline for the completion of the tebuthiuron registration review.

Registration Review for Tebuthiuron Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and Public Comment Period for Preliminary Work Plan	September 2009
Close Public Comment	November 2009
Case Development	
Final Work Plan	March 2010
Issue Data Call-In	Oct. – Dec. 2010
Data Submission	Oct. – Dec. 2012
Open Public Comment Period for Preliminary Risk Assessments	Apr. – June 2014
Close Public Comment Period	July – Sept. 2014
Registration Review Decision	

Open Public Comment Period for Proposed Registration Review Decision	Oct. – Dec. 2014
Close Public Comment Period	Jan. – Mar. 2015
Final Registration Review Decision and Begin Post-Decision Follow-up	2015
Total (years)	**6**

Summary of Comments and Agency Responses:

During the public comment period, the Agency received comments from Dow AgroSciences L.L.C., FIFRA Endangered Species Task Force (FESTF), the United States Department of Agriculture (USDA), and other interested stakeholders. The comments and EPA's responses are presented below.

Summary of Comments Submitted from Dow AgroSciences on the Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessments for Tebuthiuron

Comment: EPA stated that an evaluation of potential risk to Threatened and Endangered Species (TES) will be undertaken as part of the EPA registration review; however, this work has already been done. In their proposal for the use of herbicides in vegetation management programs on BLM-managed lands, the federal Bureau of Land Management (BLM) has recently finalized their "programmatic Environmental Impact Statement for Vegetation Treatments Using Herbicides on Bureau of Land Management Lands in 17 Western States" (the "PEIS"). Dow AgroSciences has summarized this document for the convenience of EPA, and submitted it on April 23, 2009. This document has been submitted to the tebuthiuron registration review docket.

Response: The Agency will evaluate the results, tools, and procedures provided in the submitted document entitled "Tebuthiuron – Use of Land Management Assessments to Fulfill ESA Consultation". However, the scope of uses considered for the consultation conducted on BLM-managed lands is different than the scope of uses considered for the registration review assessment. Because the registration review assessment will consider uses both on and off BLM-managed land, the previous consultation, which considered only tebuthiuron uses on BLM-managed lands, is not fully applicable to registration review.

Comment: As noted in the 1994 RED and the June 15, 2009 Memorandum entitled *Registration Review Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessment for Tebuthiuron,* tebuthiuron is stable in water through hydrolysis and photolysis and has relatively long half-lives in aerobic and anaerobic aquatic metabolism studies. These data indicate that little or no useful information could be obtained from an aquatic field dissipation study. Further, Dow AgroSciences removed the use on ditch banks in the early 1990s and as the only aquatic use, the aquatic dissipation study is no longer required.

Response: Under registration review, the Agency will consider all uses. Currently, the ditch bank use is included on the label of registration number 34913-10. Thus, the Aquatic Field Dissipation study remains an anticipated data requirement.

Comment: The marine/estuarine fish acute toxicity study (850.1075) was waived in a Memorandum dated February 27, 1987, and the waiver was also reiterated in the 1994 RED. The Agency determined that the study was not required in light of tebuthiuron's extremely low toxicity to freshwater fish and marine and freshwater invertebrates.

Response: Although the tebuthiuron Reregistration Eligibility Decision (RED) waived the acute estuarine/marine fish toxicity study, the Agency needs these data now in order to be able to perform a national-scale assessment that would allow a determination of whether consultation on listed estuarine/marine fish is necessary. If estuarine/marine fish are more sensitive than freshwater fish to a degree proportionate to the sensitivity differences between estuarine/marine and freshwater invertebrates, then it is possible that tebuthiuron concentrations in surface water might reach levels that would exceed the endangered species level-of-concern. Therefore, without these data, the Agency would have to assume that tebuthiuron might pose a risk to estuarine/marine fish, and would have to initiate consultation with the Services once the risk assessment has been completed.

Comment: An embryo larval toxicity study (MRID 00041684) was previously submitted and declared as meeting the guideline requirements in a February 27, 1987 Memorandum and reiterated as acceptable in the 1994 RED .

Response: The Agency concurs with Dow regarding the previously submitted embryo larval toxicity study. This study is classified as acceptable and fulfils the guideline requirement for acute embryo larval toxicity studies. However, the 40 CFR Part 158 also requires a bivalve acute toxicity shell deposition study for pesticides that may potentially enter waterways. Therefore, the Agency continues to anticipate the need to require the submission of a bivalve acute toxicity on shell deposition study per guideline 72-3(b) (850.1025).

Comment: A crustacean acute toxicity study (00041684) was previously submitted and declared as meeting the guideline requirements in a February 27, 1987 Memorandum and reiterated as acceptable in the 1994 RED.

Response: The Agency concurs with Dow AgroSciences regarding the previously submitted crustacean acute toxicity study testing the pink shrimp. This study has been reviewed and is classified as acceptable for fulfilling the acute crustacean toxicity study guideline requirement.

Comment: Two studies (freshwater fish early life-stage) were previously submitted on fathead minnow (MRID 00090084) and rainbow trout (MRID 00090083). Both studies were declared acceptable and met the requirement and guideline.

Response: The Agency concurs with Dow AgroSciences regarding the previously submitted studies. These studies were reviewed and classified as acceptable for fulfilling the requirement and guideline for a freshwater early life-stage study (OPPTS Test guideline No. 850.1400; 72-4(a).

Comment: A study on Daphnia magna was previously submitted (MRID 00138700) and declared as meeting the requirement and guideline in a February 27, 1987 Memorandum and reiterated as acceptable in the 1994 RED.

Response: The Agency concurs with Dow AgroSciences regarding the previously submitted freshwater invertebrate life cycle study testing Daphnia magna. This study has been reviewed and classified as acceptable for fulfilling the requirement and guideline for a freshwater invertebrate life cycle study (OPPTS Test guideline No. 850.1300).

Comment: A Tier I seedling emergence toxicity study (41066901) was previously submitted in April 1989, and declared as an acceptable Tier II study in the 1994 RED. Although the study title states "Tier I", this study is a full dose response (6 dose levels) experiment on 10 plant species and thus is a true Tier II study. This study also included vegetative vigor measurements. Therefore, further plant testing is not scientifically warranted for either formulation type.

Response: Because of the lack of either a Tier II seedling emergence study testing the typical end-use product (TEP) of tebuthiuron or a Tier II vegetative vigor study testing the TEP of tebuthiuron, the Agency is unable to conclude with certainty that the TEP of tebuthiuron will not pose a more significant risk to nontarget terrestrial plants than the technical grade active ingredient (TGAI). An acceptable study on a TEP remains a data gap and will be included in the data call-in.

Comment: Two avian reproduction toxicity studies are available for tebuthiuron (MRID 00104243 and 00093690) for bobwhite quail and mallard duck. The studies indicated low toxicity with both NOEL values >100 ppm, the highest concentration tested. In the preliminary problem formulation for ecological risk and environmental fate, endangered species and drinking water assessments, the Agency anticipated that application of tebuthiuron at the highest envisaged rate of 6 lb. ai/A may lead to upper bound residues on small insects of 810 ppm which is higher than the dietary concentrations tested in the existing avian long-term studies. It should however be considered that the residues used in T-REX for insects are derived from the Hoerger and Kenaga (1972) data which has been modified by Fletcher et al. These data are based on residues measured on vegetation as a surrogate for insects with similar surface area to mass ratios. Residues on real insects have been measured in recent European studies and are summarized in an opinion prepared by the European Food Safety Authority (EFSA) Plant Protection products and their Residues (PPR) Panel for use in risk assessment.

Response: The Agency will examine the information that Dow AgroSciences has provided regarding the European studies mentioned in their comment. However, the Fletcher monogram remains the standard method used to estimate potential exposures to

pesticides. Therefore, the submission of a guideline study (GLN 850.2200) that exposes birds at or above levels estimated to be found on potential food items of birds remains a data gap. Without the submission of such a study, the Agency cannot preclude potential risks to birds.

Summary of Comments from Dow AgroSciences on the Registration Review Scoping Document for Tebuthiuron

Comment: Tebuthiuron is only used for the restoration of natural grassland vegetation in rangeland, permanent pastures and in non-cropland areas such as energy and transportation rights-of-way. Annual grasses have a low tolerance to tebuthiuron and can be significantly damaged by broadcast applications as low as 0.3 lb a.i./acre. Since tebuthiuron is a residual herbicide that expresses its activity over several years, use on annual crops is precluded.

Response: Dow AgroSciences provided clarifying information regarding use of tebuthiuron which indicates that most land treated is not retreated for 10 to 15 years, if ever. Dow also indicated that damage may occur to perennial grasses due to tebuthiuron's persistent residual herbicidal activity. Based upon this and other substantive information received, the Agency concurs that Dow has provided adequate information pertaining to pasturelands and perennial grasses; therefore a rotational crop study is not required.

Comment: Dow AgroSciences agrees to provide an Immunotoxicity study (870.7800) for tebuthiuron to upgrade the registration package and address this new guideline. We look forward to discussion of the timeline for the conduct and submission of this information.

Response: The Agency looks forward to discussing the timeline and submission of the Immunotoxicity study.

Comment: In the Tebuthiuron Registration Review Scoping Document for Human Health Assessments, a neurotoxicity battery (acute and sub-chronic neurotoxicity) was highlighted as a data gap for the tebuthiuron registration review process. Dow AgroSciences believes that existing studies for tebuthiuron provides an adequate degree of confidence that tebuthiuron does not present a neurotoxic hazard. Dow AgroSciences respectfully requests a waiver be granted for the requirement for the acute and sub-chronic neurotoxicity studies for tebuthiuron.

Response: The Agency has re-evaluated the available toxicity database for the pesticide tebuthiuron to look at its neurotoxicity potential. Upon evaluation of the available studies along with the information that Dow AgroSciences provided (use pattern in years and the use on non-crop land areas) during the 60-day comment period, the Agency will not require the acute and sub-chronic neurotoxicity studies for tebuthiuron.

Comment from Dow AgroSciences Regarding the Submission of a Tebuthiuron Benefits Assessment

Comment: Dow AgroSciences would like to assist the Agency in the registration review of tebuthiuron; therefore, we submitted a Tebuthiuron Benefits Assessment during the pubic comment period. This assessment carefully documents the critical benefits of an irreplaceable herbicide for the restoration of natural grassland vegetation in rangeland, permanent pastures, and non-cropland areas.

Response: The Agency thanks Dow for providing the benefit assessment for tebuthiuron, and will consider this information as it conducts the tebuthiuron registration review.

Comment from FESTF

Comment: FESTF stated that its data on endangered species proximity contained in the FESTF Information Management System (FESTF IMS) and NatureServe data submissions to the Agency (MRIDs 46325901, 46486301, and 47260101) "fulfill the data requirements, and provide the best available data necessary for the proximity analysis of tebuthiuron use and listed species locations." FESTF stated that the leading registrants, as identified in the Registration Review Summary Document are Dow AgroSciences LLC (Dow) and Celsius Property B. V. Dow is a current member of FESTF, and as such, is entitled to the FESTF data on federally-listed threatened and endangered species. However, Celsius Property B.V. is not a FESTF member.

Response: The Agency thanks FESTF for its comment, and will consider this information as it conducts the tebuthiuron registration review.

Comment from USDA

Comment: Tebuthiuron is a valuable product that we now have to use to combat the fast approaching strangulation of our rangelands by noxious brush, and must be allowed to remain on the market. This product is many times our only way to economically and effectively deal with many species of brush and weeds. The Federal Government cost shares thousands of acres of brush management each year with producers using this product through the EQIP program that is vital to the safe keeping of our rangelands. Tebuthiuron is a key player in this business and must be kept available to use as a method to combat brush and weeds on American rangelands.

Response: The Agency thanks USDA for its comment, and will consider this information as it conducts the tebuthiuron registration review.

Summary of Comments from 19 Other Interested Stakeholders

Comments: The Agency received 19 comments from other interested stakeholders who support the continued registration of tebuthiuron. Tebuthiuron is a critical tool for the management and restoration of rangeland. It is the only tool available to control many of the invasive brush species that are currently taking over our rangelands and their ecosystems. In the railroad market tebuthiuron provides residual vegetation control at

railroad crossings, specifically around crossing signals and battery boxes. For many electric utilities, tebuthiuron is an indispensable tool in the management of vegetation on rights-of way, substations, and plant sites. Woody vegetation on power line rights-of-way is a leading cause of power outages. Federal agencies such as the Federal Aviation Administration, the Bureau of Prisons, the Department of Defense, and the Department of Energy also depend on tebuthiuron to help maintain vegetation on the facilities.

Response: The Agency thanks the interested stakeholders for their comments, and will consider this information as it conducts the tebuthiuron registration review.

Next Steps

The Agency plans to issue a DCI in late 2010 requiring the tebuthiuron studies needed to complete both the ecological and human health risk assessments. The Agency will conduct an ecological risk assessment, an endangered species assessment, and a human health risk assessment for tebuthiuron.